

## REMARKS

### **1. Claims**

Claims 129 – 135, 137 – 138 and 148 – 165 are pending. Claims 1 – 128, 136 and 139 – 147 are Canceled. Claims 129 – 130, 132 – 135, and 137 – 138 are Amended. Claims 148 – 165 are New.

Claim 130 is amended to correct the misspelling of poly(ethylene glycol).

Claim 134 is amended to remove the limitation of “islet” from the cell contained in the microcapsule.

Claim 135 is amended to correct the misspelling of “fluorescein”, “erythrosin”, and “phloxine”.

Claims 148-165 are added to obtain previously unclaimed disclosures.

### **2. Compliance with 35 U.S.C. § 102/103**

The Examiner has rejected Claims 1 and 129-138 under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al. (5,700,848 or 5,705,270 or 5,846,530). In addition, the Examiner has rejected Claims 1 and 129-138 under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al. (5,545,423, or 5,759,578 or 5,788,988 or 5,879,709).

In response to the above grounds of rejection, Applicants submit a Declaration under 37 C.F.R. § 1.131 by Amar Sawhney (“Sawhney Declaration”), a co-inventor of said application. Applicants submit that the Declaration establishes invention of the subject matter of the rejected claims prior to the effective date of the cited references.

The Sawhney Declaration states that before October 29, 1991; that is before Soon-Shiong ‘848 was filed; the co-inventors (Hubbell, Pathak, Sawhney and Desai) reduced to practice in the United States “a method of encapsulating biological materials, which comprises mixing the biological material with a polymer, forming microcapsules, coating the microcapsules with a photoinitiator, mixing the microcapsules containing the biological material in an aqueous macromer, polymerizing the gel using a light source, and generating macrocapsules” (Sawhney Declaration, paragraph 5). The Sawhney Declaration, which is supported by attached Exhibits 1 & 2, describes encapsulation of microcapsules into macrocapsules of poly(ethylene oxide).

In paragraph 10, the Sawhney Declaration states that the Examiner has also cited Soon-Shiong et al., U.S. Patent Numbers 5,545,423; 5,759,578; 5,788,988 and 5,879,709; which have a filing date (November 25, 1991) later than Soon-Shiong '848, '270 and '530 and that consequently, the invention as claimed was also completed before this date.

Additionally, in response to the above grounds of rejection, Applicants submit a Declaration under 37 C.F.R. § 1.131 by Jeffrey A. Hubbell ("Hubbell Declaration"), a co-inventor of said application. Applicants submit that the Declaration establishes invention of the subject matter of the rejected claims prior to the effective date of the cited references of Soon-Shiong et al. ('848, '270, '530, '423, '578, '988 and '709).

The Hubbell Declaration states that before Soon-Shiong '848 was filed, that is, before October 29, 1991, Jeffrey Hubbell described in a letter a "PEG gel method for encapsulation" which "allows us to build up a layer of PEG gel around an algin-PLL-algin capsule" (Hubbell Declaration, paragraph 9).

In paragraphs 10 to 22, the Hubbell Declaration states that before October 29, 1991 Jeffrey Hubbell in an Invention Disclosure to the University of Texas at Austin presented the details of "Laser Photopolymerized Gels for the Encapsulation of Cells" which describes encapsulation of microcapsules into macrocapsules of poly(ethylene glycol) (supported by attached Exhibit B).

In paragraphs 25 and 26, the Hubbell Declaration states that before October 29, 1991 Jeffrey Hubbell wrote three (3) confidential Invention Disclosures: "PEO gels for the encapsulation of biological materials", "Visible laser polymerized polyethylene glycol) gel coatings for enhanced biocompatibility", and "Biodegradable, cell nonadhesive hydrogels from water soluble, photopolymerizable precursors" (supported by attached Exhibit C). Important features included "to treat microcapsule membranes containing living cells", "polymerization of a macromolecular precursor", and "fast reactions and visible light" (supported by attached Exhibit D).

In view of the above, withdrawal of the cited grounds of rejection is respectfully requested.

### **3. Double Patenting**

Claims 1 and 129-138 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of U.S. Patent No. 5,529,914.

Claims 1 and 129-138 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,258,870.

Claims 1 and 129-138 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,858,746.

Claims 1 and 129-138 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,801,033.

Additionally, Claims 1 and 129-138 possibly will be rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of newly issued U.S. Patent No. 6,911,227.

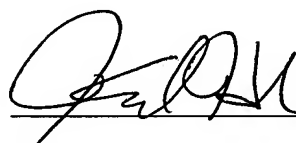
The above grounds of rejection under the judicially created doctrine of obviousness-type double patenting are believed to be obviated by Applicants' Terminal Disclaimer submitted herewith.

Application No.: 10/761,180  
Filing Date: January 20, 2004

### CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Date: March 12, 2005



Kirk Hahn, Ph.D.  
Agent of Record  
Registration Number: 51,763  
Customer Number: 036,647  
(949)-727-1942 ext. 217